



HEALTHCARE REFORM

Biosimilars Law in Limbo: An Update on Biosimilars and Politics

By Brian Dorn

On March 23, 2010, the Biologics Price Competition and Innovation Act (BPCIA) was signed into law as part of the larger healthcare reform bill, the Patient Protection and Affordable Care Act (PPACA) of 2010. The BPCIA is designed to create an approval pathway for biological products that are demonstrated to be highly similar to FDA-approved biological products. Although the biosimilars law was enacted, it is not a settled matter. The political debate between supporters and opponents is still ongoing regarding many aspects of the PPACA. In fact, opponents are attempting to block the law's implementation via various means. The politics are relevant since the BPCIA could be subsumed into the political

battle over the PPACA as a whole. This article will address the potential effects of different legal and legislative scenarios and discuss whether the biosimilars law could change.

Legal. The PPACA has been challenged in court and will surely be reviewed by the United States Supreme Court. Although it is beyond the scope of this article to analyze the constitutional issues, court challenges may apply to biosimilars since the PPACA lacks a severability clause. Many laws contain a severability clause stating that an unconstitutional provision does not affect any unrelated provision(s) within the law, thereby "severing" the unconstitutional provisions from the rest of the law. Thus, it is possible that the biosimilars pathway can be struck down by a ruling of unconstitutionality of a single provision in the PPACA.

At the district court level, the constitutionality of the PPACA has been challenged five times as of March 1, 2011. The Western District of Virginia, the Eastern District of Michigan and the District of Columbia have held upheld the constitutionality of the PPACA. However, the Eastern District of Virginia and the Northern District of Florida, in lawsuits brought by the



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attorney generals of their respective states (the Florida attorney general was joined by the attorney generals of 25 other states), both ruled that the individual mandate of the PPACA is unconstitutional as it exceeds the limits of the Commerce Clause. The “individual mandate” is a provision that requires all individuals to have a health care plan from a private insurer or be monetarily penalized. The Northern District of Florida also rejected the government’s assertion that the individual mandate was a proper exercise of Congressional authority in view of the Necessary and Proper Clause.

Of the two decisions that found the individual mandate unconstitutional, one severed the individual mandate from the rest of the PPACA and the other did not. In the Florida decision, the judge did not sever the individual mandate stating, “if that goal would be undermined if a central part of the legislation is found to be unconstitutional, then severability is not appropriate.” The decision asserted that Congress acknowledged that the individual mandate was “essential” to the Act’s goals. Thus, the Florida court invalidated the entire PPACA. In contrast, the Eastern District of Virginia severed the individual mandate and directly dependent provisions. In the decision, the judge noted that the severability issue was difficult to analyze due to the bill’s lack of legislative history and thus decided on the side of judicial restraint, i.e., partial invalidity.

These two determinations of unconstitutionality have been appealed to the fourth and eleventh circuit courts of appeal. Oral arguments were held in March and June, respectively, with decisions still forthcoming. The U.S. Supreme Court will ultimately decide this matter. If the Supreme Court finds

the individual mandate constitutional or unconstitutional but severable, the BPCIA will remain untouched by the constitutional challenge. However, if the Supreme Court upholds the decision of the Northern District of Florida, the BPCIA would be invalidated with the rest of the PPACA. In that case, a biosimilars law would need to be redrafted and passed again.

Legislation. The PPACA is a politically polarizing issue and voting was mostly along party lines. The bill passed through a legislative mechanism known as reconciliation. The Senate took a House bill, deleted all of the text, and added the PPACA by amendment. The Senate passed the bill 60-39 with all Democrats and Independents (who caucused with the Democrats) voting for and all Republicans voting against. The bill then passed the House of Representatives 219 (all Democrats) to 212 (178 Republicans and 34 Democrats).

After the midterm elections of 2010, the Republicans are now in the majority in the House of Representatives (242 to 193). The Democrats are still in the majority in the Senate (53-47), but no longer maintain the filibuster-proof majority (60). On January 19, 2011, the Republican-led House majority passed a bill to repeal the PPACA in its entirety (H.R. 2). However, the bill did not pass the Senate (47-51). Thus, a Congressional repeal of the PPACA in its entirety will not happen during the 112th Congress. For a complete repeal to be possible, the voting patterns of the midterm election of 2010 would have to continue in 2012. Republicans would need to maintain its majority in the House of Representative and gain a majority, maybe even a filibuster-proof majority, in the Senate. Republicans would also need to win the

presidential election, or enough senate seats to override a veto by the President (this also assumes that current support and opposition are maintained by both political parties). If Republicans control the White House and both houses of Congress after the 2012 election, then a full repeal of the PPACA would be possible, if not probable.

If the entire PPACA is repealed, the BPCIA (i.e., the biosimilars pathway) would be repealed as well. The litigation scheme and the exclusivity set forth in the BPCIA cannot be created by FDA rulemaking. Under this scenario, Congress would have to pass a biosimilars pathway, either using the current BPCIA or drafting a different version. Although a new biosimilars bill would likely be based on the current BPCIA, certain provisions of the biosimilars law (e.g., market exclusivity) would be debated and could change.

If the entire PPACA is not repealed, opponents have proposed repealing many parts of the law (e.g., the excise tax on medical devices (H.R. 436) and have been successful in repealing the 1099 provision (H.R. 4 signed into law on April 14, 2011).

Opponents of the PPACA have also discussed trying to prevent the law’s implementation by defunding aspects that are required by the law (e.g., the new agencies created). Again, if the option is defunding, the biosimilars provisions are likely to be untouched, as well as the funding for FDA in regards to biosimilars, in the context of this effort.

Further Congressional Consideration. Separate from the repeal efforts, legislators may still attempt to amend the BPCIA. The PPACA was passed with a focus on health care reform rather than biosimilars. Therefore, the provisions of

the BPCIA were not debated in the context of passing this particular bill.

Closer examination of individual provisions of the BPCIA may lead legislators to re-examine particular provisions of the law. In fact, Commissioner of Food and Drugs Margaret Hamburg has received four separate letters from Congress regarding interpretation of the BPCIA. Many commentators and FDA interpreted the BPCIA as providing four years of data exclusivity and 12 years of market exclusivity. In letters from Senators Sanders, Hagan, Natch, Enzi and Kerry, as well as Representatives Eshoo, Inslee and Barton, all asserted that the 12-year exclusivity period was data exclusivity and not market exclusivity. Further clarifying, the bipartisan letters also stated that a biosimilars application could be reviewed after four years as provided in the BPCIA but could not rely on the reference prod-

uct sponsor's data until after 12 years. However, the bipartisan letter from U.S. Senators Brown, McCain, Schumer and Harkin on January 24, 2011, supported the view that the 12-year exclusivity period is market exclusivity and that FDA can review applications during that time period (i.e., a four-year data exclusivity period). The letters from Senators Brown et al. and Sen. Sanders noted their continued opposition to a 12-year exclusivity period, although four of the five voted in favor of its enactment. This is further confirmation that the bill passed in the shadow of the bigger health care reform debate. Therefore, members of Congress maintain differing interpretations of the statute. Congress may seek to clarify their intent through amending the BPCIA.

Additionally, the proposed U.S. government's FY2012 budget released by the White House on February 14, 2011 seeks

to reduce the 12-year exclusivity to seven years. It will be incumbent upon the legislators to enact this change.

In conclusion, the biosimilars law is not a settled matter. Opponents of the PPACA are continuing legal and legislative challenges. Additionally, there is not a current Congressional consensus on the interpretation of specific provisions in the BPCIA. In an effort to clarify or to assert their interpretation, there may be attempts to amend the law. Thus, the law providing for biosimilars (the BPCIA within the PPACA) is a fluid situation and definitely not settled for the near future. For those with business in biosimilars, it would be wise to monitor the political situation since the current state of biosimilars could drastically change depending on the politics surrounding the PPACA. ▲